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Rule	*Guidance*
R 333.5701 Purpose and scope. **Rule 701. (1)** This part establishes requirements governing the use of computed tomography (CT) scanners by, or on behalf of, a health practitioner licensed under article 15 of the act, MCL 333.1101 to 333.25211.	Part 15 covers most of the CT scanners used in health care. Licensed health practitioners include MDs, DOs, DCs, DPMs, and DDSs. It does not cover CT scanners used in veterinary medicine, industry, research, or those used in radiation therapy to create 3D images.
(2) This part applies to all registrants who use a CT scanner for the intentional exposure of humans for diagnostic imaging.	
(3) A CT scanner is exempt from this part if the scanner meets 1 of the following: (a) Generates a peak power of 5 kilowatts or less as certified by the manufacturer. (b) Is used only for attenuation corrections and anatomical markers	Examples of units exempted by this rule: • Most, if not all dental CT scanners. • Most, if not all ENT CT scanners. • PET/CT or SPECT/CT unless the CT portion is used alone for

as part of a positron emission tomography (PET/CT) or single photon emission computed tomography (SPECT/CT) study. (c) Is used as a simulator solely for treatment planning purposes in conjunction with a megavoltage radiation therapy unit. (d) Is used solely for intra-operative guidance tomography.	diagnostic imaging studies. • Therapy CT simulators unless the CT scanner is used for diagnostic imaging studies. • Mobile CT scanners used in hospitals solely for surgical applications.
(4) In addition to the requirements of this part, all registrants are subject to applicable parts of these rules and the certificate of need review standards for computed tomography scanner services.	All CT facilities must also follow all other applicable parts of the *Ionizing Radiation Rules Governing the Use of Radiation Machines*, such as Part 2 (registration), Part 3 (standards for protection against radiation), Part 4 (notices, instructions and reports to workers) and applicable rules in Part 7 (medical x-ray installations). In addition, CT facilities must also meet the certificate of need (CON) review standards for CT.
R 333.5703 Definitions. **Rule 703. (1)** As used in this part the definitions in 21 C.F.R. 1020.33, "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available for no cost from either of the following sources: (a) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss. (b) The website of the United States department of health & human services, U.S. food and drug administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.	21 C.F.R. 1020.33 contains the federal performance standards for CT equipment. Part 1020 sets the national standards for manufacture and installation of ionizing radiation emitting products in the United States.
(2) As used in this part the following definitions apply: (a) "Computed tomography (CT)" means the production of a tomogram by the acquisition and computer processing of x-ray transmission data. Computed tomography includes the capability of producing axial tomograms. (b) "CT medical event" means an unintended event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual due to or suspected to be due to exposure to diagnostic radiation from a CT scanner. (c) "CT scanner" means a CT machine capable of performing CT	"CT medical event" is an event that is reportable under R 333.5715. If a physician determines that actual physical damage has occurred to a patient due to or thought to be due to radiation exposure from a CT scanner, a CT medical event has occurred and needs to be reported.

scans of the head, other body parts, or full body patient procedures including PET/CT and SPECT/CT scanner hybrids if used for CT only procedures. (d) "Medical physicist" means an individual trained in evaluating the performance of CT scanners, related equipment, and facility quality assurance programs and who meets the requirements in R 333.5707. (e) "Positron emission tomography (PET)" means an imaging technique that uses positron-emitting radionuclides to produce 3-dimensional images of functional processes in the body. (f) "Radiologic technologist" means an individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements in R 333.5705. (g) "Single photon emission computed tomography (SPECT)" means an imaging technique that uses radionuclides to produce 3-dimentional images of functional processes in the body. (h) "Tomogram" means the depiction of the attenuation properties of a section through a body.	
R 333.5705 CT operators. **Rule 705.** All CT examinations shall be performed by a radiologic technologist who meets all of the following requirements or by a physician or osteopathic physician licensed under article 15 of the act. (a) Initial qualifications. Before beginning to perform CT examinations independently, a technologist shall meet both of the following: (i) Be currently registered by the American registry of radiologic technologists (ARRT), the Canadian association of medical radiation technologists (CAMRT), or the Nuclear Medicine Technology Certification Board (NMTCB). (ii) Document at least 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection	R 333.5705 specifies a CT scanner may only be operated by a physician licensed in Michigan or by a radiologic technologist. To demonstrate compliance with R 333.5721(a), facilities will need to maintain a list of all CT operators and proof that each operator meets the requirements of this rule. Documentation must be maintained on file and made available for inspection. Documentation for employees no longer employed must be kept until the next inspection by the department. For physician operators, a copy of their current medical license is all that is necessary. For non-physician operators, facilities must maintain:

or have the advanced certification in computed tomography from the ARRT. (b) Continuing education. A technologist shall be in compliance with the ARRT requirements for continuing education for the imaging modality in which he or she performs services. The continuing education shall include credits pertinent to CT.	• A copy of the technologist's current ARRT, CAMRT, or NMTCB registry card. • Evidence that the technologist has the advanced certification in CT from the ARRT or has received 20 hours of training and experience in operating CT equipment, radiation physics, and radiation protection. • Training programs or facilities can count on-the-job training performing supervised CT examinations toward the 20 hour total. As guidance, however, no more than 10 hours of the required 20 should come from on-the-job training. If on-the-job training was obtained from more than one entity, each entity must provide its own letter documenting those areas that it covered. • Documentation of initial qualifications could be a letter or other document from the training program, a letter or other document confirming in-house or formal training, CEU certificates or ARRT(CT) certificate. • Evidence that all technologists obtained at least 2 CT credits in the 24 months immediately preceding their birth month. • For CAMRT or NMTCB registered technologists, facilities will need evidence that the technologist obtained at least 24 credits in the 24 months immediately preceding their birth month (which is the ARRT continuing education requirement).
R 333.5707 Medical physicist. **Rule 707.** A registrant with 1 or more CT scanners shall employ or contract with a medical physicist to review the quality and safety of the operation of the CT scanner. The medical physicist shall meet all of the following: (a) Initial qualifications. Before beginning to independently provide consultation to a CT facility, a medical physicist shall meet 1 of the following: (i) Be certified in diagnostic radiological physics or radiological physics by the American board of radiology, or in diagnostic imaging	Under this part, each CT facility must employ or contract with a medical physicist. The medical physicist must meet the requirements of R 333.5707. The medical physicist may meet the initial qualifications by 1 of 2 methods: • Be board-certified. • Have a graduate degree in medical physics or other relevant

physics by the American board of medical physics, or in diagnostic radiology physics by the Canadian college of physicists in medicine. (ii) Have a graduate degree in medical physics, radiological physics, physics, or other relevant physical science or engineering discipline from an accredited institution and have formal coursework in the biological sciences with at least 1 course in biology or radiation biology and 1 course in anatomy, physiology, or similar topics related to the practice of medical physics, and have 3 years of documented experience in a clinical CT environment. An accredited institution is a college or university accredited by a regional accrediting organization that has been recognized either by the U.S. department of education (USDE) or by the council for higher education accreditation (CHEA) or both. Individuals with non-U.S. degrees shall provide documentation that their foreign degrees are equivalent to those granted from an approved institution in the U.S. and that the granting institution is equivalent to a regionally accredited institution in the U.S.	field, have taken specified courses, and have 3 years of experience in a clinical CT environment. The Radiation Safety Section will review initial qualifications if requested and issue a letter or certificate of qualification. Facilities will need to maintain evidence that their medical physicist meets the requirements of R 333.5707. Documentation must be maintained on file and kept current pursuant to R 333.5721(a). Documentation for employees no longer employed must be kept until the next inspection by the department.
(b) Continuing experience. Within 24 months following the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have evaluated at least 2 CT scanners in the prior 24-month period.	To meet the continuing experience requirement, the medical physicist must survey at least 2 CT scanners every 24 months. Surveys of the same CT scanner are acceptable. The 24-month time period is a floating time period, which means at any point in time the medical physicist must have surveyed 2 CT scanners in the previous 24 months.
(c) Continuing education. Within 36 months following the date when the requirements of subdivision (a) of this rule were completed, the medical physicist shall have earned at least 15 continuing medical education units, at least half shall be category 1, in the prior 36-month period. The continuing education shall include credits pertinent to CT.	The medical physicist must obtain at least 15 units (hours) of continuing education every 3 years. At least half (7.5 hours or more) of the physicist's continuing education must be recognized as category 1 and must include more than 1 credit in CT. The 36-month time period is a floating time period, which means at any point in time the medical physicist must have 15 continuing education units earned in the previous 36 months.
(d) Reestablishing qualifications. A medical physicist who fails to maintain the required continuing experience or continuing education requirements shall reestablish his or her qualifications before resuming the independent evaluation of CT scanners and facilities, as follows: (i) A medical physicist who fails to meet the continuing experience requirements of subdivision (b) of this rule shall evaluate a sufficient number of CT scanners, under the supervision of a medical physicist,	If a medical physicist gets behind in his or her continuing experience or continuing education, he or she must obtain additional experience or education before resuming independent evaluations of CT scanners

to meet the requirements of subdivision (b) of this rule. (ii) A medical physicist who fails to meet the continuing education requirements of subdivision (c) of this rule shall obtain a sufficient number of additional continuing education credits to meet the requirements of subdivision (c) of this rule.	
R 333.5709 Equipment requirements. **Rule 709. (1)** The regulations in 21 C.F.R. 1020.33(c), (d), (f), (g), (h), (i), and (j), "Computed tomography (CT) equipment" (June 10, 2005), are adopted by reference. Copies of these regulations are available for no cost from either of the following sources: (a) The website of the Michigan department of licensing and regulatory affairs, radiation safety section at http://www.michigan.gov/rss. (b) The website of the United States department of health & human services, U.S. food and drug administration at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm.	Some examples of equipment requirements listed in 21 C.F.R. 1020.33 include: • Indication of CT conditions of operation (kVp, mA, slice thickness, filtration, etc.) • Tomographic plane indication and alignment • Beam on and shutter status indicators • Scan increment accurate to within 1 mm • A method to calculate the mean and standard deviation of the CT number must be provided.
(2) CT equipment shall be maintained in compliance with the requirements of subrule (1) of this rule.	The federal performance standards apply to the manufacture and installation of ionizing radiation emitting products. This subrule states that the equipment must be kept in the same condition as when it was installed.
R 333.5711 Enclosures. **Rule 711. (1)** A fixed CT scanner enclosure shall be a permanent part of the building or equipment. Portable shields shall not be used for permanent installations.	The rules pertaining to enclosures are existing requirements in Part 7 and are being restated in the CT Scanner Part.
(2) The degree of protection required for a CT scanner enclosure shall be determined by the workload, use and occupancy factors, and the tube potential, tube current, mechanical movement, and distance. The design shall be subject to approval by the department.	Departmental approval of shielding for CT scanner enclosures is required through our existing radiation shielding plan review process.
(3) Protective barriers shall be provided in the ceiling, floor, and walls of a fixed CT scanner enclosure.	As used in the *Rules*, "fixed" means a machine that cannot be moved within a building or vehicle. A CT scanner installed in a vehicle that

	moves to different host sites is considered to be contained in a fixed enclosure. A mobile CT scanner is a machine that can be moved within a building, typically moved to or within an operating room or intensive care unit.
(4) The control panel for a fixed CT scanner shall be shielded by a protective barrier which cannot be removed from a protective position between the operator and the radiation source during machine operation.	
(5) Movable barriers with electrical interlocks shall not be approved in place of compliance with subrule (4) of this rule.	
(6) The operator of a fixed CT scanner shall be able to see and communicate with the patient from a shielded position at the control panel. When an observation window is provided, it shall have a lead equivalence at least equal to that required of the control barrier in which it is installed.	
(7) Mobile or portable CT scanners used routinely in 1 location shall be considered a fixed installation and shall meet the requirements of subrules (1) to (6) of this rule.	If a mobile CT is covered by this part, then it can only be used when it is medically inadvisable to move a patient to a fixed CT scanner. If it is used routinely in a single room, that room would have to be shielded to meet the requirements of subrules (1) to (6).
R 333.5713 Conditions of operation. **Rule 713. (1)** The CT facility shall establish scanning protocols in consultation with the medical physicist.	It is very important that a CT interpreting physician review the scanning protocols in consultation with the medical physicist to ensure that protocol settings are appropriate for each study and that patient dose will be kept to the practical minimum consistent with clinical objectives. All CT facilities must have reviewed their scanning protocols to ensure they are appropriate. How the review is accomplished and the determination of what is appropriate is left to the experience, knowledge and professional judgment, of both the physician and medical physicist. We will expect to see documentation that the protocols have been reviewed and determined to be appropriate. Protocols for each study performed at the facility need to be reviewed.

(2) The CT operator shall check the display panel before and after performing each scan to make sure the amount of radiation delivered is appropriate for the technique and individual patient. This may be accomplished by reviewing dose indicator devices, if available, or dose indices such as the technique factors. Dose indicators or indices outside of expected values shall be documented and reviewed by an interpreting physician or medical physicist.	Before and after each scan the operator must check the display panel to determine if the appropriate amount of radiation was used for the scan. There is no requirement to document the operator's routine check of the display panel. Only doses that are thought to be outside of expected values need to be documented and reviewed by the medical physicist or interpreting physician. The procedure a facility will use for checking the display panel should be included in the facility's quality assurance manual and shared with the CT operators. Inspectors will review the procedure the facility uses to check the display panel and document doses outside of expected values. Documentation of doses outside of expected values will also be reviewed during an inspection.
(3) A fixed CT scanner shall be operated from a shielded position behind a protective barrier pursuant to R 333.5711(4).	This rule replaces the "arm's length" rule found in Part 7 of the *Rules*. Operators must remain behind the control barrier when operating a CT scanner and should be able to comfortably operate the machine from that protected position.
(4) Staff personnel routinely working with or around radiation sources shall not be required by the registrant to restrain patients during CT examinations. If the procedure is permitted personnel exposure shall not exceed the limits in R 333.5057 to R 333.5059 or the procedure is prohibited.	The remaining sub rules in the "conditions of operation" section are all existing requirements in Part 7 of the *Ionizing Radiation Rules of Michigan* and are simply being restated in the CT Scanner Part. No inspection changes are contemplated.
(5) When a patient must be held in position for CT, mechanical supporting or restraining devices shall be used unless contraindicated. If the patient is held by an individual, this individual shall wear protective gloves and a protective apron of 0.5 millimeter minimum lead equivalence and be so positioned that no part of his or her body is struck by the useful beam and that his or her body is as far as possible from the edge of the useful beam.	
(6) Only individuals whose presence is necessary are allowed in a fixed CT scanner room during exposure. Each individual, except the patient, shall be protected by at least 0.5 millimeter lead equivalent aprons or a whole body protective barrier.	

(7) Personnel monitoring is required in controlled areas for each individual occupationally exposed to ionizing radiation from CT scanner equipment. Individual monitoring devices shall be permanently assigned to each occupationally exposed individual. Monitoring shall be continuous during employment as a radiation worker.	
(8) Personnel exposure records shall be kept on permanent available file at the facility where the exposure occurs.	
(9) Monitoring devices used to estimate whole body exposure shall normally be worn on the chest or abdomen. Monitoring of all other body parts shall meet the requirements of R 333.5065.	
(10) Monitoring devices worn to estimate personnel occupational exposure shall not be worn by the individual when he or she is exposed as a patient for a medical or dental reason.	
(11) A CT scanner shall not be left unattended without locking the apparatus, room, or building in some manner which prevents use of the apparatus by unauthorized persons.	
R 333.5715 Report and notification of CT medical event. **Rule 715. (1)** A CT facility shall report all CT medical events.	The definition of a CT medical event is included in R 333.5703(2)(c). "CT medical event" means an event where a physician determines that actual damage has occurred to an organ or a physiological system of an individual exposed to diagnostic radiation from a CT scanner.
(2) The registrant shall submit a written report to the department within 15 days after a physician of the CT facility discovers the CT medical event or within 15 days after the CT facility is notified of the CT medical event by another physician, whichever comes first.	The registrant must submit a written report to the department within 15 days of the discovery of the event. The information that is required to be included in the report is outlined in subrule (3). Information that may lead to the identification of the patient should not be included in the report pursuant to subrule (4).
(3) The written report shall include all of the following: (a) The registrant's name, address, facility registration number, and machine registration tag number as they appear on the registration certificate. (b) The name of the physician who determined a CT medical event	A guideline for reporting CT medical events, Form MIOSHA-RSS-111, is available on our website at www.michigan.gov/rss.

occurred. (c) The dates of occurrence and discovery of the CT medical event. (d) A narrative description of the CT medical event. (e) The cause of the CT medical event. (f) The effect on the individual who received the exposure. (g) A narrative detailing corrective action taken or planned to prevent a recurrence. (h) Certification that the registrant notified the individual or the individual's responsible relative or guardian and, if not, why not. (i) The name and signature of the person preparing the report.	
(4) The report shall not contain the name of the individual who is the subject of the CT medical event or any other information that could lead to identification of the individual.	The registrant must inform the referring physician and the patient or the patient's responsible relative or guardian of the CT medical event within one week of discovery or as soon as possible thereafter.
(5) The registrant shall provide notification of the CT medical event to the referring physician and shall notify the individual who is the subject of the CT medical event not later than 1 week after its discovery, unless the referring physician personally informs the registrant that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The notification of the individual who is the subject of the CT medical event may be made instead to that individual's responsible relative or guardian. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 1 week, the registrant shall notify the individual as soon as possible thereafter. The registrant shall not delay appropriate medical care for the individual, including all necessary remedial care as a result of the CT medical event, because of a delay in notification. If a verbal notification is made, the registrant shall inform the individual or appropriate responsible relative or guardian that a written description of the CT medical event can be obtained from the registrant upon request. The registrant shall provide a written description if requested.	The registrant does not have to notify the patient if the referring physician states that he or she will notify the patient or if the referring physician believes that notifying the patient could be harmful.

R 333.5717 Quality control program. **Rule 717. (1)** A CT facility shall establish and implement a quality control program under the supervision of the medical physicist. The documented program shall include evaluation of all of the following: (a) Image quality. (b) Patient radiation dose. (c) Personnel radiation protection. (d) Compliance with the provisions of this part. (e) Ongoing quality control.	Each CT facility must establish a written quality control program that is appropriate for their facility and use of their scanners. Each facility along with the medical physicist may determine the appropriate tests and methods they wish to use to evaluate each of the required items.
(2) Evaluations and tests shall be performed following written procedures and methods. Corrective action shall be taken and documented according to instructions provided by the medical physicist if the results of an evaluation or test fall outside the control limits.	Written procedures for evaluating, testing, and for taking corrective action must be established and approved by the medical physicist. The procedures should include the tests to be performed, the frequency of those tests, how to perform each test, and when corrective action must be taken.
(3) The medical physicist shall determine the frequency of each test and who may perform the test. An on-site CT radiologic technologist shall be identified to be responsible for the ongoing quality control testing. The tests shall be performed by this technologist or by other personnel qualified by training and experience following written procedures and methods under subrule (2) of this rule.	Only individuals approved by the medical physicist may perform quality control tests. Each CT facility must designate an on-site lead technologist to be responsible for the ongoing quality control program. That technologist must perform the quality control tests or must ensure that the tests are performed by an approved individual.
R 333.5719 Initial and annual medical physicist performance evaluations. **Rule 719. (1)** A medical physicist shall complete an initial performance evaluation of the CT scanner before use on human patients and annually thereafter.	The medical physicist will need to perform an initial onsite evaluation whenever a CT scanner is installed. The physicist should verify to the facility that the scanner passed the evaluation before the scanner can be used on patients.
(2) A calibrated dosimetry system shall be used to measure the	The dosimetry system used by the medical physicist to measure

radiation output of a CT scanner. Calibration of the dosimetry system shall be within the preceding 24 months and shall be traceable to a national standard as specified in R 333.5012(1).	patient dose should be calibrated at appropriate x-ray beam qualities used in diagnostic x-ray. The equipment needs to be calibrated once every 24 months by a calibration laboratory that participates in proficiency testing with NIST.
(3) A performance evaluation should include the following: (a) Alignment light accuracy. (b) Alignment of table to gantry. (c) Table and gantry tilt. (d) Slice localization from scanned projection radiograph. (e) Table increment accuracy. (f) Slice thickness. (g) Image quality, including the following: (i) High-contrast resolution. (ii) Low-contrast resolution. (iii) Image uniformity. (iv) Noise. (v) Artifact evaluation. (h) CT number accuracy and linearity. (i) Dosimetry, including the following: (i) Dose indicator such as computed tomography dose index (CTDI). (ii) Patient radiation dose for representative examinations. (j) Safety evaluation, including the following: (i) Visual inspection. (ii) Audible and visual signals. (iii) Posting requirements. (iv) Scattered radiation measurements. (k) Review of the ongoing quality control program, including test results and corrective action.	As guidance, a list of items that should be evaluated is provided in the rule. The list is the same as those recommended by the American College of Radiology's (ACR) CT accreditation program. Tests to evaluate clinical image quality, patient radiation dose, personnel radiation protection, compliance with the provisions of this part, and the ongoing quality control program must be included pursuant to R 333.5717(1).
(4) The medical physicist shall prepare a report that includes all of the following: (a) A summary of the performance evaluation required under subrule (1) of this rule.	The medical physicist must prepare a written report that includes a summary of his or her evaluation of the CT facility, any recommendations for improvements, and the type and calibration date of the dosimetry system used.

(b) Recommendations for necessary improvements. (c) Type of dosimetry system used, including the date of the last calibration.	
(5) The report required under subrule (4) of this rule shall be provided to the CT facility within 30 days after completion of the evaluation.	The CT facility must receive a copy of the report no later than 30 days after the evaluation is completed.
R 333.5721 Records and report retention. **Rule 721.** A CT facility shall maintain records and reports on file and shall make the records and reports available for review by the department as follows:	Records and reports required under this part need to be maintained on file and made available for review during inspections.
(a) Records of personnel no longer employed by the CT facility shall be kept on file until the next inspection following the employee's termination has been completed and the department has determined that the facility is in compliance with the CT personnel requirements.	Personnel documentation for each operator and medical physicist will need to be retained at the facility or made available electronically during the inspection. If a person leaves employment of the facility, the documentation for that person must be retained until the next inspection. After the department has reviewed the documentation of the person who has left, that documentation may be destroyed.
(b) A report of a CT medical event required under R 333.5715 shall be maintained on file for at least 7 years.	Reports of CT medical events must be retained for 7 years.
(c) Initial and annual medical physicist performance evaluation reports required under R 333.5719(4) shall be maintained on file for at least 5 years.	Medical physicist performance evaluations must be retained for 5 years.
(d) Records of the results from the ongoing quality control evaluation required under R 333.5717 shall be maintained on file for at least 2 years.	Records of ongoing quality control evaluations must be kept for 2 years.